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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,643	10/19/2001	Mika Jokinen	TUR -115	4103

7590 04/08/2003  
James C Lydon  
Suite 100  
100 Daingerfield Road  
Alexandria, VA 22314

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/08/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/913,643

Applicant(s)

JOKINEN ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ✓ 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

Examiner acknowledges receipt of declaration, IDS and preliminary amendment A filed 10/19/01, letter with notice of acceptance filed 01/18/02, supplemental IDS filed 07/25/02 and response to lack of unity filed 01/10/03.

#### ***Election/Restrictions***

The restriction under the lack of unity practice required in paper number 10 is withdrawn because applicants' argument is found persuasive.

#### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84. Copy of Notice of Draftsperson's Patent Drawing Review, Form Pto-948, is attached. The objection to the drawings will not be held in abeyance.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-15 and 24-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "controllably biodegradable" in claims 1, 5, 8-15, 24 and 28 is vague and indefinite because it is not clear what the phrase "controllably biodegradable" means. What is "controllably biodegradable"? How does the "controllably biodegradable" fit into the preparation of the silica fiber in claims 1, 5, 8-15, 24 and 28?

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For examination purposes, claims 1 and 5 are interpreted as method of preparing silica fiber for claim 1 and method of preparing fiber for claim 5 and the phrase does not have any patentable weight in the said claims.

Regarding claim 1, it is unclear how the viscosity of the silica sol controls the starting point of the spinning process. Does it mean that the spinning of the sols starts when the sol attains or reaches a certain viscosity? It appears from the prior art and from page 10, lines 7 and 8 of applicants specification that spinning starts when the sol reaches a certain viscosity. For examination purposes, the spinning process in claim 1 starts when the sol attains a certain viscosity.

Claim 1 recites the limitation "the starting point" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 1 recites the limitation "the viscosity" in line 3. There is insufficient antecedent basis for this limitation in the claim.

For examination purposes, the phrase "controllably biodegradable" in claims 8-15, 24 and 28 is not considered. Claims 8-15, 24 and 28 are interpreted as being directed to silica fiber or fiber.

4. Claim 8 recites the limitation "the starting point" and "the spinning process" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

5. Claims 16 and 20 recite the limitation "the biodegradation" in line 1. There is insufficient antecedent basis for this limitation in the claim.

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***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (US 4,919,871).

Lin discloses a method of preparing fibers from sol-gel compositions and the method comprises dry spinning sol of suitable viscosity through an orifice (abstract, column 2, lines 19-27). The sol-gel of Lin is prepared from tetraethoxysilane (TEOS), ethylsilicate 40, which is a partially condensed tetraethylorthosilicate (TES) (column 2, lines 28-66) and the sol is a silica sol since it is formed from silicates. The sol formed in example XII is aged to a room temperature viscosity of 129 poise (12900 mPa.s) and the composition is formed or spun into fibers at said viscosity of 129 poise. See also claims 1-8 of Lin. The viscosity of 129 Poise or 12,900 mPa.s is below 100,000 mPa.s as recited in claims 2, 5, 9 and 13 and lies between the viscosity ranges in claims 3, 4, 6, 7, 10, 11, 14 and 15. Claim 8 is directed to fiber that is obtained from a sol and the biodegradation property of the fiber is inherent. Lin discloses fibers that are obtained from sol and thus meets the limitations of the scope of the claim. Thus, in light of the above discussion, Lin meets the limitations of the claims.

8. Claims 1-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahola et al. (WO 97/45367, provided by applicants on Form PTO-1449).

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Ahola discloses silica-xerogels produced by sol-gel process (abstract, page 1, lines 22-30 and claim 1). In Ahola the sol is formed into small particles by spray drying or fiber spinning or by drawing technique (page 3, lines 29-33). Ahola discloses sustained and/or controlled release delivery devices comprising the silica-xerogel particles and biological agents; Ahola discloses a method of administering biologically active agents to a human or animal where the method comprises implanting or injecting or transmucosally attaching to a human or animal body a delivery device, wherein the delivery device comprises silica-xerogel that undergoes controlled dissolution and where the silica-xerogel particle/fiber spun from a sol-gel comprises has biologically active agent incorporated therein (page 4, lines 1-18 and claims 13-22). Ahola discloses that silica-xerogel particles undergo controlled dissolution over a period of time and that the biologically active agents incorporated into the particles also undergo controlled release (page 4, line 25 to page 5, line 27). Ahola further discloses production of fibers from the silica-xerogels by sol-spinning technique conducted at room temperature (page 9, line 27 to page 10 line 17). In example 2, Ahola produces silica fibers by drawing the fibers in spinneret reactor at a starting sol viscosity of 10 mPa.s and this viscosity is less than 100,000 mPa.s. A viscosity of 10 mPa.s also lies within the viscosity ranges of 1,000 to 15,000 mPa.s and 2,000 to 50,000 mPa.s.

Reading claims 16 and 20 in light of the specification clearly shows that the method for controlling the biodegradation of silica fiber is related to the dissolution of the silica fiber and said dissolution is influenced by the viscosity at which spinning begins (example 3 of the instant specification). Ahola also teaches that the silica-xerogel or the silica-xerogel fiber comprising biologically active agents undergoes controlled dissolution and controlled release of the

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biologically active agents. Since the silica-xerogel fiber of Ahola is produced by spinning the sol-gel and since the spinning starts at a specific viscosity that accords the fiber its properties, Ahola inherently teaches the method of claims 16 and 20 and the viscosity of 10 mPa.s at which the spinning starts in Ahola meets the viscosity limitations of claims 2-7, 9-11, 13-15, 17-19 and 21-23.

Thus Ahola anticipates the claims as discussed above.

9. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is respectfully requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara  
Patent Examiner  
Tech. Center 1600  
April 7, 2003

